



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<b>DECLARATION UNDER 37 C.F.R. 1.132</b>  Address to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Attorney Docket No.	CALD-007
	First Named Inventor	Caldwell, Larry
	Confirmation Number	3764
	Application Number	10/029,407
	Filing Date	November 13, 2000
	Group Art Unit	1615
	Examiner Name	Ghali, Isis D.
	Title:	Methods and compositions for treating headache pain with topical NSAID compositions

Dear Sir:

I, Bradley Galer, am an inventor of the subject matter claimed in the patent application identified above. Enclosed is a copy of my C.V. which demonstrates that I am qualified to speak on the level of one of skill in the art.

I hereby declare as follows:

1. I have read both the Advisory Action dated November 16, 2005 and the Office Action dated July 28, 2005 that issued in the above referenced case. I have also read the WO 97/17978 (WO '978) publication, the reference cited in support of the rejections made by the Examiner.

2. The WO '978 publication discloses a pharmaceutical composition, and a method of using the same, containing an administration medium that includes a solution of nitrous oxide in water and an analgesic, anti-inflammatory, and/or an anti-pyretic drug.

3. Based on my review of the WO '978 publication, one of skill in the art would understand the nitrous oxide disclosed therein to be an active agent, despite its characterization to the contrary by the Office.

4. One of skill in the art would understand nitrous oxide to be an active agent because of the teachings set forth in the following references:

**1. Nitrous Oxide Revisited: Evidence for Potent Antihyperalgesic Properties. Richebe P, Rivat C, Creton C, Laulin JP, Maurette P, Lemaire M, Simonnet G., *Anesthesiology*, 2005 Oct, 103(4):845-854.**

**2. Effect of nitrous oxide in reducing pain of propofol injection in adult patients. Sinha PK, Neema PK, Rathod RC., *Anaesth Intensive Care*, 2005 Apr, 33(2):235-8.**

**3. Nitrous oxide for the treatment of acute migraine headache. Triner WR, Bartfield JM, Birdwell M, Raccio-Robak N. *Am J Emerg Med*. 1999 May;17(3):252-4.**

5. All of these references teach that nitrous oxide is an active agent. For instance, Richebe et al. sets forth a study in rats wherein the ability of nitrous oxide to prevent opiate-induced hyperalgesia is tested. The results of the study indicate that because nitrous oxide has anti-N-methyl-d-aspartate properties it is effective in reducing inflammation induced by hyperalgesia. These results suggest that perioperative nitrous oxide use reduces postoperative pain. Additionally, Shina et al. sets forth a randomized, double blind study in humans wherein the efficacy of pretreatment with nitrous oxide for

the prevention of propofol-induced pain was tested. The results indicate that an inhalation of 50% nitrous oxide reduces pain on propofol injection. Triner et al conducted a randomized double-blind controlled trial in patients presenting to an emergency department with migraine headache and found that nitrous oxide showed efficacy in alleviated the migraine.

6. Accordingly, in light of these teachings, one of skill in the art would recognize that nitrous oxide is an active agent. As such, the WO '978 publication teaches nitrous oxide as an active agent.

I hereby declare that all statements made herein are of my own knowledge and are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued there from.

Date: January 5, 2006  
(e-signature)

Respectfully submitted,

Bradley S. Galer, M.D.

Bradley Galer

enc:

- CV of Dr. Bradley Galer

## **Bradley Stuart Galer, M.D.**

1740 Lenape Road, Bldg 2  
West Chester, PA 19382  
Phone (610) 737-6927  
Email: bgaler@topiceutical.com

### **Personal Data**

Date of Birth: July 21, 1961  
Place of Birth: Boston, Massachusetts  
Family: Wife - Anna  
Children - Alexander, Peter, & Simon

### **Education**

Albert Einstein College of Medicine, 1983-1987  
Bronx, New York  
Degree: M.D., June 1987

Wesleyan University, 1979-1983  
Middletown, Connecticut  
Degree: B.A., Biology-Psychology, June 1983

### **Postgraduate Training**

Internship: Kaiser Foundation Hospital, 1987-1988  
Oakland, California

Residency: Albert Einstein Neurology Residency Program, 1988-1991  
Bronx, New York

Chief Resident: Albert Einstein Neurology Residency Program, 1990-1991  
Bronx, New York

Headache Training Montefiore Headache Clinic, 1990-1991  
Bronx, New York

Headache Training University of California San Francisco, 1992  
San Francisco, CA

Pain Fellowship: Memorial Sloane-Kettering Cancer Center, 1990-1991 (4 months)  
New York, New York (Drs. Kathleen Foley and Russell Portenoy)

Pain Fellowship: University of California San Francisco, 1991-1992  
San Francisco, CA (Drs. Howard Fields and Michael Rowbotham)

Business School Wharton Executive Education, 2002; Business Leadership Training  
  
Harvard Business School Executive Education, 2005  
Leadership & Strategy in Pharmaceutical and Biotech

Industry Positions

## TOPICEUTICAL INC

- Chairman of the Board, CEO, President. October 2005 - present

## ENDO PHARMACEUTICALS INC

- Group Vice President, Scientific Affairs & Senior Medical. August 2003- September 2005.
- Vice President, Scientific Affairs & Senior Medical Officer. August 2000- August 2003

## CALDWELL-GALER INC

- Co-Founder, Chairman of the Board. September 1997 – November 2005

Other Industry Experience

- 1992-98, co-lead investigator and co-developer clinical development plan for Lidoderm
- 1998, originator and lead coordinator of Endo's licensing Lidoderm from Hind Health Care

Industry Roles & Responsibilities

## ENDO (2000- present)

- Reported directly to Executive Vice President
- Direct reports included Clinical Research, Clinical Operations, Medical Affairs, Safety Pharmacovigilance and Risk Management, Clinical Development and Education, Pharmacoeconomics
- Provide clinical and scientific leadership for the development and marketing of analgesic products
- Design clinical development plans and protocols for registration and market support (Phase I-IV)
- Assist in regulatory strategy
- Writing and editing of clinical study reports
- Writing and editing of NDA
- Lead cross-functional project teams in the execution of phase I-IV clinical trials ensuring successful studies in accordance with GCP/ICH guidelines
- Interpret clinical data
- Directly interface with FDA
- Direct scientific dissemination of data via publications and presentations
- Lead Endo medical/clinical representative to press
- Clinical and scientific lead in business development with assessment of licensing opportunities
- Lead Medical Liaison Group with Thought Leader development and all educational initiatives
- Reviewed all clinical sections of regulatory documents including study reports, INDs, NDAs, annual reports, Investigator Brochures and labeling
- Prepare annual budgets for Scientific Affairs (up to \$25 million)

## Bradley Stuart Galer, M.D.

### Drug Development Experience

Lidoderm®	1991-1999	Regulatory strategy, Phase 3 study design/execution (Hind Health Care, Consultant)
	2000-2005	Life Cycle Management (LCM) strategy/execution (Endo)
Oxymorphone ER/IR	2000-2005	Phase 1-3 regulator strategy, study design/execution, NDA preparation (Endo)
Oxydone ER generic	2000-2004	Clinical review of Paragraph 4, development of Risk Management Program (Endo)
DepoDur®	2003-2005	NDA preparation, LCM (Endo)
Percocet®	2000-2005	LCM (Endo)
MorphiDex®	2000-2003	Regulatory strategy, Phase 3 study design/execution (Endo)
Neurontin	1995-2000	Phase 3 study design, LCM (Parke-Davis, Pfizer, Consultant)
Lyrica	1998-2000	Phase 3 study design/execution (Pfizer, Consultant)
Effexor	1995-1997	Phase 3 study design/execution (Wyeth, Consultant)
Tizanidine	1998-2000	LCM (Elan, Consultant)
ABT-484	1995-1998	Phase 2 POC study design (Abbott, Consultant)
GV196771	1998-2000	Phase 2 POC study design/execution (Glaxo Wellcome, Consultant)
Topical Clonidine	1996-2000	Regulatory Strategy, Phase 2/3 study design (Curatek, Lead Consultant)

### Faculty Positions Held

Acting Assistant Professor of Anesthesia/Adjunct Assistant Professor of Neurology  
University of Washington School of Medicine  
Seattle, Washington  
1992- 1994

Assistant Professor of Anesthesia/Adjunct Assistant Professor of Neurology  
University of Washington School of Medicine  
Seattle, Washington  
1994 – April 1996

Assistant Professor of Neurology/Adjunct Asst. Professor of Anesthesiology  
Washington School of Medicine  
Seattle, Washington  
May 1996 - May 1998

Associate Professor of Neurology  
Albert Einstein College of Medicine  
Bronx, NY  
1999-2000

### Faculty Positions Held (cont'd)

Adjunct Assistant Professor of Neurology (Associated Faculty)  
University of Pennsylvania School of Medicine  
Philadelphia, Pennsylvania  
October 2001 – October 2004

University of Washington Medical Center Positions Held (1993 - May 1998)

Attending, Multidisciplinary Pain Center  
Director, Pain Clinical Research Center  
Medical Director, Headache Program  
Medical Director, Reflex Sympathetic Dystrophy Program

Beth Israel Medical Center Positions Held (May 1998 – August 2000)

Attending, Pain Division of the Department of Pain Medicine & Palliative Care  
Attending, Department of Neurology  
Director of Clinical Studies, Institute for Education and Research  
in Pain & Palliative Care  
Co-Director, Nerve Pain Disorders Clinic

Board Certification

American Academy of Pain Management, November 1, 1996 {Certificate # 6712}

Honors

Keeney Scholarship, for Achievement in Academics and Community Involvement  
Wesleyan University, 1981-1983

Phi Beta Kappa  
Wesleyan University, 1982-1983

Doyle Award, Medical Student with Highest Achievement in Neurology  
Medical Degree with Special Distinction in Clinical Neurology Research (Pain)  
Albert Einstein College of Medicine, 1987

Young Investigator Travel Award, American Pain Society, 1991

“Best Doctors in America: Pacific Region, 1996-1997; 1998-1999, Neurology  
(Pain Management)

“Best Doctors in America,” 1998 (entire USA, Pain Management/Neurology)

“Tele Award,” (for best medical documentary, cable TV)- Co-write and Co-host,  
“Understanding Shingles”, 2000

Honors (Cont'd)

## **Bradley Stuart Galer, M.D.**

First "Annual Neuropathy Organization Honoree," (for work in neuropathic pain),  
New York City, 2004

### **Academic Memberships**

International Association for the Study of Pain (IASP)  
Neuropathic Pain, Sympathetic Nervous System and RSD/CRPS Special Interest Group (IASP)  
International Headache Society  
American Headache Society  
American Pain Society  
American Academy of Pain Medicine  
American Academy of Pain Management  
American Association for the Study of Headache  
American Academy of Neurology  
Reflex Sympathetic Dystrophy Syndrome Association  
Phi Beta Kappa

### **Academic Administrative Duties**

Reflex Sympathetic Dystrophy Program, University of Washington, 1993 - May 1998;  
develop comprehensive multidisciplinary outpatient program,  
(physicians, psychology, physical therapy, occupational  
therapy, vocational counselor, and nursing)

Pain Clinical Research Center, University of Washington, 1992 - May 1998;  
Founder; obtain, protocol development, perform, and supervise pain clinical research  
staff, (pharmaceutical industry clinical trials and other clinical research activities);  
3 research coordinators and 3 research assistants

Director of Clinical Studies, Institute for Education and Research in Pain  
& Palliative Care, Beth Israel Medical Center, May 1998 – 2000

Group Vice President, Scientific Affairs. Endo Pharmaceuticals Inc.  
Supervise 45 persons. Responsible for Clinical Operations, Clinical Research, Medical  
Affairs, and Clinical Development & Education. August 2000- present. Active in  
clinical trial design, portfolio strategy, pharmacovigilance and safety, publication  
planning, educational course development, business development and marketing strategy.

### **Special Responsibilities – Elected Boards, Editorials and Journal Reviewer**

Director at Large (elected), Eastern Pain Association (2002- *present* )



Board of Directors, Reflex Sympathetic Dystrophy Syndrome Association (2002- *present* )  
 Founding Editor and Editor, *Current Pain and Headache Reports* (1999 – *present*)  
 Editorial Board, *The Clinical Journal of Pain* (2000 - *present*)  
 Associate Editor, *The Clinical Journal of Pain* (1998 - 2000)  
 Editorial Board, *Journal of Back and Musculoskeletal Rehabilitation*  
 Editor, *Progress in Pain for Primary Care* (1999-2000)  
 Book Editor, *Journal of Pain and Symptom Management* (1998-2000)  
 Series Editor, *Progress in Pain for Primary Care*  
 Supplement Editor, *Neurology Reviews Supplement: Management of Neuropathic Pain*  
 Supplement Editor, *The Clinical Journal of Pain: International Conference of Neuropathic Pain*  
 Expert Analyst Editor, *The Pain Medicine Journal Club Journal*  
 Ad Hoc Reviewer, *JAMA*  
 Ad Hoc Reviewer, *Pain*  
 Ad Hoc Reviewer, *American Family Physician*  
 Ad Hoc Reviewer, *Journal of General Internal Medicine*  
 Ad Hoc Reviewer, *Journal of Pain and Symptom Management*  
 Ad Hoc Reviewer, *Pharmacoeconomics*

#### Other Responsibilities

Invited Member, IMMPACT (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials), closed round-table with FDA, Academia, NIH, and Industry, 2002- *present*  
 Invited Member, Promoting the Health of People with Disabilities (CDC)-Diabetes Task Force, 1992, 1993  
 Consultant, Quality of Life in Migraine Study-University of Washington Department of Health Services Cost and Outcome Assessment Team, 1993  
 Medical Student Research Training Program Advisor, 1993  
 Consultant, Cost and Effectiveness of Care for Chronic Conditions-Center for Health Studies, 1994  
 Education Committee- American Academy of Pain Medicine, 1995-96  
 Invited author, presenter, participant - 1995  
     USA Congressional NIH Report-Chronic Pain and Peripheral Neuropathies  
 Advisor, American Board of Pain Medicine- Certification Examination, 1997  
 Pain Medicine Section of American Academy of Neurology  
     Founding Member and Executive Committee, 1995- *present*  
     Vice-Chairman, Chairman elect - 1996-97  
     Co-Chairman, Education Committee, 1995 - *present*,  
     Chairman, 1998-2000  
 Chairman of Professional Development Courses. American Pain Society's 18<sup>th</sup> Annual Conference, 1998-1999.  
 Panel member, Cancer Pain Management Guideline Panel, Clinical Practice Guidelines Program, American Pain Society, 1999

#### Other Responsibilities (cont'd)

Founder, National Director, National Conferences on Pain Management for the Primary Care Physician (American Pain Society), 1998-2001  
 Co-Chairman / Steering Committee, Annual International Neuropathic Pain Conference,

## **Bradley Stuart Galer, M.D.**

1998-present

Workshop Organizer and Moderator, IASP 9<sup>th</sup> World Congress on Pain,  
“Prognostic Utility of Intravenous Infusion Treatment of Neuropathic Pain: Lidocaine,  
Opioid, and Phentolamine,” 1999  
IASP 2<sup>nd</sup> Annual Research Symposium- Founder and co-chair, “CRPS.” Wales, UK. 2000  
Key role in establishment of Endo sponsored “Essentials of Pain Management Program for  
Residents,” 2002 - present

### **Invited Advisory Panels/Boards/Consultation**

Chair and Moderator, National Drug Advisory Board Meeting, Parke-Davis, 2000

Advisory Boards:

Pfizer

Merck Research

Abbott Laboratories

Roche Bioscience

Watson Pharmaceutical

Consultant, Elan Pharmaceutical

Consultant, GlaxoWellcome

Emerging Concepts of Anticonvulsants for Chronic Pain – 1996

Consultant, Myelos Neurosciences- 1998

National Guidelines for Neuropathic Pain Treatment for the Primary Care Physician - 1997

National Guidelines for Pain Management in Long-Term Nursing Facilities -  
1997, 1998

Management of Pain, Myofascial Pain Syndromes - 1998

Participant, International Neuropathic Pain Treatment Guideline Consensus Meeting- 2001

### **Invited Non-Profit Organizations Board Membership**

Reflex Sympathetic Dystrophy Syndrome Association- 2002-present

### **Patents- Issued (USA)**

1. Method for Treating Headache Pain with Topical Local Anesthetic Compositions  
Inventor: CALDWELL LARRY; GALER BRADLEY STUART  
Assignee: TOPICEUTICAL INC
2. Method for Treating Neuroma Pain  
Inventor: GALER BS; CALDWELL J  
Assignee: CALDWELL GALER INC

### **Patent Applications (publicly disclosed)**

1. Methods and compositions for treating headache pain with topical NSAID compositions  
Inventor: CALDWELL LARRY; GALER BRADLEY STUART  
Assignee: TOPICEUTICAL INC
2. Methods for treating indomethacin responsive headaches

Inventor: GALER BRADLEY S; NEWMAN LAWRENCE  
Assignee: TOPICEUTICAL INC

3. Methods and compositions for treating carpal tunnel syndrome (topical NSAID)  
Inventor: CALDWELL LARRY; GALER BRADLEY STUART  
Assignee: CALDWELL GALER INC
4. Compositions and methods for treating neuropathic sensory loss  
Inventor: GALER BRADLEY S  
Assignee: ENDO PHARMACEUTICALS INC
5. Abuse-resistant opioid dosage formulations  
Inventor: GALER BRADLEY; KAO HUAIHUNG D  
Assignee: ENDO PHARMACEUTICALS INC
6. Method for deterring abuse of opioids by combination of non-release formulation of emetic  
Inventor: GALER BRADLEY STUART; GAMMAITONI ARNOLD  
Assignee: ENDO PHARMACEUTICALS INC
7. Method for treating non-neuropathic pain  
Inventor: STUART GALER BRADLEY  
Assignee: ENDO PHARMACEUTICALS INC
8. Composition and method for treating neuropathic sensory loss.  
Inventor: DWORKIN ROBERT D; GALER BRADLEY STUART  
Assignee: ENDO PHARMACEUTICALS INC
9. Abuse resistant pharmaceutical composition containing capsaicin  
Inventor: GOLDBERG M; GALER B S  
Assignee: ENDO PHARMACEUTICALS INC
10. Abuse-resistant opioid solid dosage form  
Inventor: KAO HUAIHUNG; GALER BRADLEY  
Assignee: ENDO PHARMACEUTICALS INC
11. Pharmaceutical composition and method for treating disorders of central nervous system.  
Inventor: GALER BRADLEY S; SCHLAGHECK THOMAS G  
Assignee: ENDO PHARMACEUTICALS INC
11. Abuse resistant pharmaceutical composition containing capsaicin  
Inventor: GOLDBERG MICHAEL; GALER BRADLEY STUART  
Assignee: ENDO PHARMACEUTICALS INC

### Businesses

Topiceutical Inc. Founder, CEO, President. 2005 – present.

Development and commercialization of topical drugs for the treatment of pain and headache.

## **Bradley Stuart Galer, M.D.**

Caldwell Galer, Inc. (CGI) Co-Founder & Chairman of the Board. 1997 – present  
Development of topical drugs for the treatment of pain and headache.

### **Academic Funded Grants**

1993-1995, Principal investigator - "Multicenter randomized, double-blind study of the analgesic efficacy during 30 days of as needed use of topical lidocaine patches and lidocaine gel in patients with postherpetic neuralgia". Private funding: Hind Health Care, Inc.

1996-1998, Principal Investigator- "Multicenter randomized, double-blind study of the analgesic efficacy of topical lidocaine patches and lidocaine gel in patients with painful diabetic neuropathy." Private funding: Hind Health Care, Inc. /Teikoku Seiyaku Co., Ltd.

1996-1997, Principal Investigator- "Multicenter randomized, double-blind study of the analgesic efficacy of topical diclofenac patches in the treatment of acute minor sports injury pain." Private funding: Institut Biochimique SA/Teikoku Seiyaku Co., Ltd.

1996-1998, Investigator- "Multicenter randomized, double-blind study of the analgesic efficacy of venlafaxine-ER in patients with postherpetic neuralgia." Private funding: Wyeth-Ayerst Research.

1996-1998, Principal Investigator- "Double-blind, randomized, placebo-controlled, cross-over study to determine the efficacy and safety of Rilutek in subjects with peripheral neuropathic pain." Private funding: Rhone-Poulenc Rorer Pharmaceuticals.

1997-1998, Principal Investigator, "Comparision study of the analgesic efficacy and safety of transdermal versus topical clonidine gel in patients with postherpetic neuralgia." Private funding: Curatek Pharmaceuticals.

1997, Investigator- "A randomized, double-blind, placebo-controlled, two period crossover study to explore the preliminary safety, tolerability, and efficacy of oral L-754,030 in the treatment of postherpetic neuralgia." Private funding: Merck Research Laboratories.

1997-1998, Principal Investigator, "Open label pilot study of the analgesic efficacy and safety of topical clonidine in patients with reflex sympathetic dystrophy (complex regional pain syndrome)." Private funding: Curatek Pharmaceuticals.

1997-1998, Principal Investigator, "Enriched enrollment, double-blind, cross-over design study of the analgesic efficacy of topical lidocaine patches in patients with postherpetic neuralgia". Private funding: Hind Health Care, Inc.

### **Academic Funded Grants (cont'd)**

1997 - 1998, Sole Investigator, "Pain Medicine Survey of 700 Practicing Neurologists and Neurology Residency Program Directors in America," in conjunction with the American Academy of Neurology.

1998-1999, Co-Investigator, "A Double-blind Placebo-Controlled Trial of Pregabalin for Treatment of Painful Diabetic Peripheral Neuropathy." Private funding: Parke-Davis Pharmaceutical Research.

1998-1999, Co-Investigator. "Pregabalin Open-label Follow-On Safety Trial in Patients With Painful Diabetic Peripheral Neuropathy." Private funding: Parke-Davis Pharmaceutical Research.

1998-1999, Principal Investigator. "A Double-blind Placebo-Controlled Trial of Pregabalin for Treatment of Postherpetic Neuralgia." Private funding: Parke-Davis Pharmaceutical Research.

1998-1999, Co-Investigator. "Pregabalin Open-label Follow-On Safety Trial in Patients With Postherpetic Neuralgia." Private funding: Parke-Davis Pharmaceutical Research.

1998-1999. Principal Investigator. "A Pilot, Multicenter, Double-Blind, Placebo Controlled, Randomized, Cross-Over Study to Evaluate the Efficacy, Safety, and Tolerability of Remacemide Hydrochloride 600mg/day in Subjects with Moderate to Severe Neuropathic Pain." Private funding: Astra Pharmaceutical Research.

1998-1999. Principal Investigator. "A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group Evaluation of a 14 Day Course of 300mg of GV196771 in Subjects with Chronic Neuropathic Pain." Private funding: Glaxo-Wellcome Research.

1998-1999, Co-Investigator. "A Repeated-dose Evaluation of Analgesic Use and Safety of Dilaudid SR (Hydromorphone HCL) in Patients with Chronic Cancer Pain." Private funding: Knoll Pharmaceutical.

1998-1999, Co-Investigator. "A Randomized, Double-blind, Placebo-controlled Efficacy, Safety and Outcomes Trial of Controlled Release-Oxycodone (Oxycontin) in Painful Diabetic Polyneuropathy." Private funding: Purdue Pharma LP.

1999, Principal Investigator- "Multicenter randomized, double-blind study of the analgesic efficacy of topical diclofenac patches in the treatment of acute minor sports injury pain." Private funding: Institut Biochimique SA.

#### Invited Papers, Lectures, Presentations - Neuropathic Pain

University of Washington Multidisciplinary Pain Center Grand Rounds- 1991, 1992, 1993, 1994, 1995, 1996, 1997

University of Washington Neurology Grand Rounds- 1992, 1993, 1996, 1998

University of Washington Geriatric Grand Rounds- 1992

University of Washington Neurological Surgery Grand Rounds- 1992

University of Washington Treatment of Hand Problems, CME course-1994

#### Invited Papers, Lectures, Presentations - Neuropathic Pain (cont'd)

University of Washington Physical Medicine and Rehabilitation Grand Rounds- 1995

University of Washington Pain CME Course- 1994, 1996

University of Washington Physical Medicine and Rehabilitation CME Course- 1996

University of Oregon Health Sciences, Rheumatology Update, Bend, Oregon- 1993

Saint Joseph Hospital, Internal Medicine Grand Rounds, Spokane, WA- 1993

## **Bradley Stuart Galer, M.D.**

Dannemiller Foundation, Pain Treatment for the Neurologist, New York- 1993  
Bremerton Naval Base Hospital, Family Medicine Grand Rounds, Bremerton, WA-1993  
Congress of Neurological Surgeons 43rd Annual Meeting, Vancouver, B.C.- 1993  
Northwest Regional Conference for Occupational/Physical Therapy, Bellevue, WA- 1993  
Kaiser Permanente Hospital, Medicine Grand Rounds, Los Angeles, CA-1994  
Kaiser Permanente Hospital, Medicine Grand Rounds, Montabello, CA-1994  
Group Health Cooperative, Medicine Grand Rounds, Redmond, WA-1994  
Providence Hospital, Medicine Grand Rounds, Yakima, WA-1994  
International Society of Critical Care Conference, San Francisco, CA- 1995  
Valley Medical Center, Pain Management Course, Renton, WA- 1995  
Maricopa Medical Center, Medical Grand Rounds, Phoenix, AZ- 1995  
Los Angeles Neurological Society, Grand Rounds, Los Angeles, CA- 1995  
Chronic Pain and Pain Mechanisms, San Francisco, CA- 1995  
American Pain Society, Los Angeles, CA- 1995  
NIH Workshop on Selected Chronic Pain Conditions, Bethesda, MD- 1995  
Emerging Applications for Anticonvulsants in the Management of Pain- Dallas, 1996  
Parke-Davis Neurology Consultants Meeting, Aspen, CO-1996  
Eastern Washington State Hospital, Spokane, WA- 1996  
Spokane Neurology Group, Spokane, WA- 1996  
Emerging Applications for Anticonvulsants in the Management of Pain-audioconference, 1996  
Emerging Applications for Anticonvulsants in the Management of Pain- Honolulu, HI; Seattle, WA; Tacoma, WA; Bellevue, WA; Spokane, WA;  
Newport Beach, CA 1996  
Private Practice Neurologists, Internists - Seattle, WA 1996  
St. John Medical Center - Longview, WA 1996  
Madigan Army Medical Center- Tacoma, WA 1996  
Spokane Primary Care Physicians- Spokane, WA 1996  
Coeur d'Alene Generalists- Coeur d'Alene, ID 1996  
Internal Medicine Review Course, Tacoma, WA 1997  
American Academy of Neurology- Boston, MA 1997  
Hawaii (7 lectures to primary care physicians/neurologists) - 1997  
Emerging Concepts of Antiepileptic Drugs- San Diego CA, Los Angeles CA,  
Las Vegas NV, Seattle WA, Pasadena CA, Snowbird Utah- 1997  
Chronic Pain Management - Swedish Medical Center, Seattle WA - 1997  
American Pain Society- New Orleans 1997  
Private Practice Neurologists - Everett, WA 1997  
Neurological Nurses Association of Washington, Seattle, WA 1998  
North Shore Medical Center, Neurology Grand Rounds, Manhasset, NY. July 1998  
Private Practice Physicians- Seattle, WA September 1998  
Neurological Institute, Columbia School of Medicine, New York, NY 1999  
Hannahan School of Medicine, Philadelphia, PA 1999  
Vanderbilt School of Medicine, Nashville, TN 1999  
Invited Papers, Lectures, Presentations - Neuropathic Pain (cont'd)

2<sup>nd</sup> World Congress in Neurological Rehabilitation, Toronto, Canada, 1999  
Neurogenic Pain, Pavia Italy, 1999  
Neurology Grand Rounds, University of Rome Italy, 1999  
International Neuropathic Pain Conference- Washington, DC, 1999  
Japan Society of Drug Delivery Systems- Takamatsu, Kagawa Japan, 1999  
Osaka Pain Group- Osaka Japan, 1999

International Association for the Study of Pain 9th World Congress on Pain (2 lectures and moderator), Vienna Austria, 1999  
University of Washington Neurology Grand Rounds, Seattle WA 2001  
University of Washington Pain Grand Rounds, Seattle WA 2001  
Washington State Annual DO Conference, Blaine WA 2001  
Georgetown Pain Grand Rounds, Washington DC 2001  
University of Utah, Annual Pain Conference, Snowbird UT 2002  
American Academy of Pain Management Nurses, Salt Lake City UT 2002  
United Kingdom Pain Society- Plenary Lecture, Bournemouth UK 2002  
Harvard Medical School Pain Course- Boston MA 2005

Invited Papers, Lectures, Presentations - RSD (Complex Regional Pain Syndromes)

University of Washington Multidisciplinary Pain Center Grand Rounds- 1991, 1992, 1993, 1994, 1995, 1996, 1997  
University of Washington Neurology Grand Rounds, 1996  
Los Angeles Neurological Society, Los Angeles, CA- 1995  
NIH Workshop on Selected Chronic Pain Conditions, Bethesda, MD- 1995  
Emerging Applications for Anticonvulsants in Pain, workshop leader, Dallas, TX- 1996  
Chronic Pain Symposium, North Shore Medical Center, NY- 1996  
American Pain Society, Washington, D.C.- 1996  
International Meeting on Neuropathic Pain, Rochester, NY. June 1998  
Hannan School of Medicine, Philadelphia, PA 1999  
Beth Israel Medical Center Neurology Grand Rounds, New York NY 1999  
IASP Research Conference, Wales UK 2000  
International Update on RSD/CRPS, Tampa FLA 2002  
Eastern Pain Society, NY, NY 2002

Invited Papers, Lectures, Presentations - Analgesic Clinical Trial Design & Pain Measurement

International Neuropathic Pain Conference, Washington DC, 2000  
American Academy of Neurology, Philadelphia PA 2001  
Residents Program, American Pain Society, Baltimore MD 2002  
American Academy of Neurology, Denver CO 2002  
World Congress of Pain, San Diego CA 2002  
International Neuropathic Pain Conference, Bermuda 2002  
Harvard Pain Course, Boston, 2005

Invited Papers, Lectures, Presentations - Headache

Medex, Physicians Assistant Program- 1993  
Multidisciplinary Pain Center Grand Rounds- 1994, 1995, 1996  
Office Management of Chronic Pain, CME course- 1994  
Neurology Grand Rounds- 1994, 1996  
Family Medicing Grand Rounds- 1994  
General Lecture to Public, University of Washington Medical Center- 1996  
Barnes & Nobles- Bellvue WA- 1997

## **Bradley Stuart Galer, M.D.**

University of Oregon Health Sciences, Rheumatology Update, Bend, Oregon- 1993  
Sacred Heart Hospital, Medicine Grand Rounds, Spokane, WA- 1993  
Bend Memorial Clinic, Family Medicine Grand Rounds, Bend, Oregon- 1993  
Portland Emergency Room Staff, Portland, Oregon- 1993  
Northwest Regional Conference for Occupational/Physical Therapy, Bellevue, WA- 1993  
Valley General Hospital, Renton, WA- 1994  
Kaiser Permanente Hospital, Portland, WA- 1994(2)  
Billings Community Hospital, Billings, MT- 1994  
Rose Medical Center, Medicine Grand Rounds, Denver, CO- 1994  
Benefits Expo (Health Care Managers), Minneapolis-1994  
Group Health Cooperative, Silverdale, WA - 1995  
Kaiser Permanente Hospital, Los Angeles, CA - 1995,1996  
Kaiser Permanente Hospital, Portland, Oregon - 1995

### **Public Media**

Television host and writer- "Understanding Shingles". The Health Network, 1999-2000, ½ hour television show for consumers.

Medical Chat Room Expert- Pain Management. Yahoo/The Health Network, 2000.

Medical Writer, "Pain" and "What's New in Pain", [www.stoppain.org](http://www.stoppain.org), 1998-2000.

### **Course Development**

Faculty, Presenter, Workshop Leader- Curriculum Development for CME Course on "Emerging Applications for Anticonvulsants in Pain," Profession Postgraduate Services, Dallas, TX- March, 1996

Co-Chair, American Pain Society 1996 Annual Meeting- Clinical Symposium, "CRPS-I (RSD)- Primarily a Disuse/Neglect-like Phenomenon Requiring Primarily a Rehabilitation Approach?", Washington, DC- October 1996

Moderator, American Pain Society 1996 Annual Meeting- Clinical Symposium, "'Psychogenic Pain'- Harmful to our Patients' Health", New Orleans, LA- October 1997

Workshop leader, Moderator, 1999 International Association for the Study of Pain, 9th World Congress of Pain - "Diagnostic, Therapeutic, and Prognostic Uses of Intravenous Infusions in Chronic Pain Syndromes," Vienna Austria, August 1999

### **Course Development (con'td)**

Chair, Program Development Courses, 1999 American Pain Society Meeting, Fort Lauderdale, Fla.

Program Development Courses, 2000 American Pain Society Meeting, Atlanta, Ga.



Chair, Program Developer, American Pain Society's National Pain Management Course for the Primary Care Physician, 1999, New York.

Co-Chair, International Neuropathic Pain Conference, 1999, Washington, DC.

Co-Chair, International Neuropathic Pain Conference, 2000, Washington, DC.

Organizing Committee, International Association for the Study of Pain Research Symposium: Complex Regional Pain Syndrome, 2000, U.K.

Co-Chair, International Neuropathic Pain Conference, 2001, San Francisco CA

Steering Committee, International Neuropathic Pain Conference, 2002, Bermuda

### Bibliography

#### Original Publications

1. Sinnamon HS, Galer BS. Head Movements Elicited by Electrical Stimulation of the Anteromedial Cortex of the Rat. *Physiol & Behav* 1984;33:185-190.
2. Lipton RB, Galer BS, Dutcher JP, Portenoy RK, Berger M, Arezzo JC, Miruchi M, Weirnik PH, Schaumburg HH. Quantitative Sensory Testing Demonstrates that Subclinical Sensory Neuropathy is Prevalent in Patients with Cancer. *Arch Neurol* 1987;44:994-996.
3. Portenoy RK, Galer BS, Salomon O, Freilich M, Finkel JE, Milstein D, Thaler HT, Lipton RB. Identification of Epidural Neoplasm: Radiology and Bone Scintigraphy in the Symptomatic and Asymptomatic Spine. *Cancer* 1989;64:2207-2213.
4. Galer BS, Lipton RB, Weinstein S, Bello L, Solomon S. Apoplectic Headache and Oculomotor Nerve Palsy: An Unusual Presentation of Multiple Sclerosis. *Neurology* 1990;40:1465-1466.
5. Galer BS, Lipton RB, Kaplan R, Kaplan JG, Arezzo JC, Portenoy RK. Bilateral Burning Foot Pain: Monitoring of Pain, Sensation and Autonomic Function During Successful Treatment with Sympathetic Blockade. *J Pain Symptom Manage* 1990;6:92-97.

#### Original Publications (cont'd)

6. Lipton RB, Galer BS, Dutcher JP, Portenoy RK, Pahmer V, Meller F, Arezzo JC, Wiernik PH. Large and Small Fibre Type Sensory Dysfunction in Patients with Cancer. *J Neurol Neurosurg Psychiatry* 1991;54:706-709.

## **Bradley Stuart Galer, M.D.**

7. **Galer BS**, Lipton RB, Solomon S, Newman LC, Spierings ELH. Myocardial Ischemia Related to Ergot Alkaloids: A Case Report and Literature Review. *Headache* 1991;31:446-450.
8. **Galer BS**, Coyle N, Pasternak GW, Portenoy RK. Individual Variability in the Response to Different Opioids: report of five Cases. *Pain* 1992;49:87-91.
9. **Galer BS**, Rowbotham MC, Fields HL. Treatment of Inflammatory, Neuropathic and Sympathetically Mediated Pain in a patient with Sjogren's Syndrome. *Pain* 1992;50:205-208.
10. **Galer BS**, Miller KV, Rowbotham MC. Response to Intravenous Lidocaine Infusion Differs Based Clinical Diagnosis and Site of Nervous System Injury. *Neurology* 1993;43:1233-1235.
11. Fitzgibbon D, **Galer BS**. Efficacy of Opiates in Cancer Pain. *Pain* 1994;58:429-31.
12. **Galer BS**, Butler S, Jensen M. Case Reports and Hypothesis: A Neglect-like Syndrome may be responsible for the Motor Disturbance in Reflex Sympathetic Dystrophy. *J Pain Sympt Management* 1995;10:385-392.
13. Von Korff M, **Galer BS**, Stang PE. Chronic Use of Symptomatic Headache Medication in Primary Care. *Pain* 1995;62:179-186.
14. **Galer BS**. Preliminary Report: Peak Pain Relief is Delayed and Duration of Relief is Extended following Intravenous Phentolamine Infusion. *Reg Anesth* 1995;20:444-447.
15. Rowbotham MC, Davies PJ, Verkempinck CM, **Galer BS**. Lidocaine Patch: Double-blind Controlled Study of A New Treatment Method for Postherpetic Neuralgia. *Pain* 1996;65:39-45.
16. **Galer BS**, Harle, J, Rowbotham MC. Response to Intravenous Lidocaine Infusion Predicts Subsequent Response to Oral Mexiletine: A Prospective Study. *J Pain Symptom Management* 1996;12:161-167.
17. Wagner TH, Patrick DL, **Galer BS**, Berzon R. A New Quality-of-Life Measure for Migraine, the MSQOL: Development and Psychometric Testing. *Headache* 1996;36:484-492.

### **Original Publications (cont'd)**

18. **Galer BS**, Jensen M. Development and Preliminary Validation of a Pain Measure Specific to Neuropathic Pain: The Neuropathic Pain Scale. *Neurology* 1997;48:332-339.
19. **Galer BS**, Schwartz L, Turner J. Do Patient and Physician Expectations Predict Pain Relief? *Clin J Pain* 1997;13:348-351.

20. **Galer BS**, Bruehl S, Harden RN. IASP Diagnostic Criteria for Complex Regional Pain Syndrome (CRPS): a preliminary empirical validation study. *Clin J Pain* 1998;14:48-54.
21. Stang P, Von Korff M, **Galer BS**. Reduced Labor Force Participation Among Primary Care Headache Patients. *Journal of General Internal Medicine* 1998;13:296-302.
23. Carter G, Jensen M, **Galer BS**, Kraft G, Crabtree L, Beardsley RM, Abresch R, Bird, T. Pain in Charcot-Marie-Tooth Disease. *Arch of Phys Med and Rehab* 1998;79:1560-1564.
24. Shibata M, Nakao K, **Galer BS**, Shimzu T, Taniguchi H, Uchida T. A Case of RSD (CRPS I) Resolved by Cerebral Contusion. *Pain*, 1999;79:313-315.
25. **Galer BS**, Rowbotham MC, Perander J, Friedman E. Topical Lidocaine patch Relieves Postherpetic Neuralgia more effectively than a vehicle topical patch: Results of an Enriched Enrollment Study. *Pain*, 1999;80:533-538.
26. Allan G, **Galer BS**, Schwartz L. Epidemiological Review of 134 Patients with Complex Regional Pain Syndrome Assessed in a Chronic Pain Clinic. *Pain*, 1999;80:539-544.
27. Harden N, Bruehl S, **Galer BS**, Salz S, Bertram M, Backonja M, Gayles, R, Stanton-Hicks M, Rudin. External Validation of IASP Diagnostic Criteria for Complex Regional Pain Syndrome and Proposed Research Diagnostic Criteria. *Pain*, 1999;81:147-155.
28. Rashiq S, **Galer BS**. Myofascial Dysfunction in Complex Regional Pain Syndrome. *Clin J Pain* 1999;15:151-153.
29. Black L, Saunders K, Von Korff M, **Galer BS**. Headache Medication Use Among Primary Care Headache Patients in a Health Maintenance Organization. *Cephalalgia*, 1999;19:575-580.
30. **Galer BS**, Jensen M. Neglect-like Symptoms in Complex Regional Pain Syndrome: Results of a Self-administered Survey. *J Pain and Sympt Manage* 1999;18:213-217.
31. **Galer BS**, Keran C, Frisinger, M. Pain Medicine Education Among American Neurologists: A Need for Improvement. *Neurology* 1999;52:1710-1712.
32. Harden N, Bruehl S, **Galer BS**, Salz S, Bertram M, Backonja M, Gayles, R, Stanton-Hicks M, Rudin. Complex Regional Pain Syndrome: Are the IASP Diagnostic Criteria Valid and Sufficiently Comprehensive? *Pain* 1999;83:211-221.

Original Publications (cont'd)

33. **Galer BS**, Friedman E, Perander J, Devers A, Ford G, Quiring J, Rowbotham M. Topical Diclofenac Patch Relieves Acute Minor Sports Injury Pain: Results of a Controlled Clinical Trial. *J Pain and Sympt Manage*, 2000;19:287-294.
34. **Galer BS**, Gianas A, Jensen. Painful Diabetic Polyneuropathy: Epidemiology, Pain Description, and Quality of Life. *Diabetes Research and Clinical Practice*, 2000;47:123-128.

## **Bradley Stuart Galer, M.D.**

35. **Galer BS.** Advances in the Treatment of Postherpetic Neuralgia: The Topical Lidocaine Patch. *Today's Therapeutic Trends*, 2000;18:1-20.
36. Cramer GW, **Galer BS**, Mendelson MA, Thompson GD.. A Drug Use Evaluation of Selected Opioids and Nonopioid Analgesics in Nursing Facilities. *J Am Geriat Soc*, 2000;48:398-404.
37. Devers A, **Galer BS**, Topical Lidocaine Patch Relieves a Variety of Neuropathic Pain Conditions: An Open Label Pilot Study. *Clin J Pain*, 2000;16:205-208.
38. **Galer BS**, Jensen M. Complex Regional Pain Syndrome: Epidemiology, Pain Description, and Quality of Life. *J Pain Symptom Manage*, 2000;20:286-292.
39. **Galer BS**, Twilling LL, Harle J, Cluff, R, Friedman E, Rowbotham MC. Lack of Efficacy of Riluzole in the Treatment of Neuropathic Pain Conditions. *Neurology*, 2000;55:971-975.
40. Gabb MG and **Galer BS**. A closer look at the tools used to diagnosis and assess neuropathic pain. *Advanced Studies in Medicine*, 2001;1:248-254.
41. **Galer BS**, Jensen M, Ma T, Davies PS, Rowbotham MC. The Lidocaine 5% Patch Effectively Treats All Neuropathic Pain Qualities: Results of a Randomized Vehicle-Controlled, Double-blind Study Using the Neuropathic Pain Scale. *Clin J Pain*, 2002;18:297-301.
42. Gammaitoni AR, Alvarez NA, **Galer BS**. Pharmacokinetics and safety of continuously applied lidocaine patches 5%. *Am J Health Syst Pharm*, 2002;59:2215-2220.
43. Wallace MS, Rowbotham M., Katz NP, Dworkin RH, Dotson RM, **Galer BS**, Rauck RL, Backonja MM, Quessy SN, Meisner PD. A randomized, double-blind, placebo-controlled trial of a glycine antagonist in neuropathic pain, *Neurology*, 2002; 59: 1694.
44. Gammaitoni AR, Alvarez NA, **Galer BS**. Safety and Tolerability of the Lidocaine Patch 5%, a Targeted Peripheral Analgesic: A Review of the Literature. *J Clin Pharmacol*, J Clin Pharmacol 2003;43:111-117.

### **Original Publications (cont'd)**

45. Gammaitoni AR, **Galer BS**, Bulloch S, Lacouture P, Caruso F, Ma T, Schlagheck T. Randomized, Double-Blind, Placebo-Controlled Comparison of the Analgesic Efficacy of Oxycodone 10 mg/Acetaminophen 325 mg vs Controlled-Release Oxycodone 20 mg in Postsurgical Pain. *J Clin Pharmacol*, 2003;43:296-304.
46. Gammaitoni AR, **Galer BS**, Lacouture PG, et.al. Effectiveness and safety of new oxycodone/acetaminophen formulation with reduced acetaminophen for the treatment of low back pain. *Pain Medicine* 2003;4:21-30.

47. **Galer BS**, Gammaitoni AR. Over 7 years of consistent neuropathic pain relief in geriatric patients. Letter. *Arch Intern Med* 2003;10;163:628.
48. Gammaitoni AR, Alvarez NA, **Galer BS**. Pharmacokinetics and Safety of Continuously applied lidocaine patch 5%. *Am J Health-Sys Pharm*. 2002;59:2215-20.
49. Oaklander AL, Bowsher D, **Galer BS**, MD, Haanpää M, Jensen MP. Herpes Zoster Itch: Preliminary Epidemiologic Data. *J Pain*, 2003;6:338-343.
50. Dworkin RH, Backonja M, Rowbotham MC, Allen RR, Argoff CR, Bennett GJ, Bushnell C, Farrar JT, **Galer BS**, Haythornthwaite JA, Hewitt DJ, Loeser JD, Max MB, Saltarelli M, Schmader KE, Stein C, Thompson D, Turk DC, Wallace MS, Watkins LR, Weinstein SM. Advances in neuropathic pain: diagnosis, mechanisms, and treatment recommendations. *Archives of Neurology*, 2003;60: 1524-1534.
51. Turk DC, Dworkin RH, Allen RR, Bellamy N, Brandenburg N, Carr DB, Cleeland C, Dionne R, Farrar JT, **Galer BS**, Hewitt DJ, Jadad AR, Katz NP, Kramer LD, Manning DC, McCormick CG, McDermott MP, McGrath P, Quessy S, Rappaport BA, Robinson JP, Royal MA, Simon L, Stauffer JW, Stein W, Tollett J, Witter J. Core outcome domains for chronic pain clinical trials: IMMPACT recommendations. *Pain*. 2003;106(3):337-45.
52. Davies PD and **Galer BS**. Review of Lidocaine Patch 5% Studies in the Treatment of Postherpetic Neuralgia. *DRUGS*, 2004;64(9):937-947.
53. **Galer BS**, Sheldon E, Patel N, Coddling C, Burch F, Gammaitoni A. Topical Lidocaine Patch 5% may target a novel underlying pain mechanism in osteoarthritis. *Current Medical Research and Opinion*, 2004;20(9):1455-1458.

#### Original Publications (cont'd)

54. Dworkin RH, Turk DC, Farrar JT, Haythornthwaite JA, Jensen MP, Katz NP, Kerns RD, Stucki G, Allen RR, Bellamy N, Carr DB, Chandler J, Cowan P, Dionne R, **Galer BS**, Hertz S, Jadad AR, Kramer LD, Manning DC, Martin S, McCormick CG, McDermott MP, McGrath P, Quessy S, Rappaport BA, Robbins W, Robinson JP, Rothman M, Royal MA, Simon L, Stauffer JW, Stein W, Tollett J, Wernicke J, Witter J. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain*, 2005;113(1-2):9-19.

## **Bradley Stuart Galer, M.D.**

55. Jensen MP, Dworkin RH, Gammaitoni AR, Olaleye DO, Oleka N, **Galer BS**. Assessment of pain quality in chronic neuropathic and nociceptive pain clinical trials with the Neuropathic Pain Scale. *J Pain*. 2005;6(2):98-106.
56. **Galer BS**, Lee D, Ma T, NagleB, Schlagheck T. Morphidex® in the treatment of chronic pain: 3 multicenter, randomized, double-blind, controlled clinical trials fail to demonstrate enhanced opioid analgesia or reduction in tolerance. *Pain*. 2005;115:284-295.

### **Multimedia**

1. **Galer, BS**. Chronic Pain and Headache- An Interactive Learning Program for Patients, Primary Care Physicians, Nurses, Physician Assistants, and Medical Students [CD-ROM], Hoffman & Associates, 2001.

### **Books**

1. **Galer, BS** and Dworkin, R. A Clinical Guide to Neuropathic Pain, McGraw-Hill Publishers, 2000.

### **Invited Review Articles / Book Chapters**

1. **Galer BS**, Portenoy RK. Acute Herpetic Neuralgia and Postherpetic Neuralgia: Clinical Features and Management. *Mt Sinai J Med* 58:257-266;1991.
2. Bowdle TA, **Galer BS**. Agonist-antagonist and Partial Agonist Opioids: Pharmacology Mechanisms and Clinical Application in the Treatment of Headache. *Headache Quarterly*, 4:322-36, 1993.
3. **Galer BS**. Painful Polyneuropathy: Diagnosis, Pathophysiology, and Treatment. *Sem Neurol*, 14:237-246, 1994.
4. **Galer BS**. Neuropathic Pain of Peripheral Origin-Advances in Pharmacologic Treatment. *Neurology*, 45(Suppl 9):S17-S25, 1995.
5. **Galer BS**, Loeser JD, Von Korff M. Painful Diabetic Neuropathy. NIH Report on Chronic Pain. 1995.

### **Invited Review Articles / Book Chapters (cont'd)**

6. **Galer BS**, Loeser JD, Von Korff M. Reflex Sympathetic Dystrophy (Complex Regional Pain Syndrome, Type 1). NIH Report on Chronic Pain. 1995.
7. Loeser JD, **Galer BS**, Von Korff M. Phantom Limb Pain. NIH Report on Chronic Pain. 1995

8. Loeser JD, **Galer BS**, Von Korff M. Postherpetic Neuralgia. NIH Report on Chronic Pain. 1995
9. **Galer BS**, Argoff C. Zoster and Postherpetic Neuralgia: Pain Mechanisms and Current Management [book chapter]. In: Aronoff, G: *Evaluation and Treatment of Chronic Pain*. Williams & Wilkens, 1998.
10. **Galer BS**. Painful Polyneuropathy. In: Backonja, M: *Neurologic Clinics*, WB Saunders, 1998.
11. Backonja M, **Galer BS**. Pain Assessment. In: Backonja, M: *Neurologic Clinics*, WB Saunders, 1998.
12. **Galer BS**, Schwartz L, Allen R. The Complex Regional Pain Syndromes - Type I / Reflex Sympathetic Dystrophy and Type II / Causalgia. In: Loeser, JM: *Bonica's Management of Pain*. 2000.
13. **Galer BS**. Topical Drugs for the Treatment of Pain. In: Loeser, JD: *Bonica's Management of Pain*. 2000.
14. **Galer BS**. Complex Regional Pain Syndrome (RSD) of the Knee. In: *Surgery of the Knee*, W.B. Saunders 2000.
15. Dworkin RH, Nagasako EM, **Galer BS**. Assessment of Neuropathic Pain. In: Turk DC, Melzack R, *Handbook of Pain Assessment*, Guilford Press, New York, In press.
16. Carter GT and **Galer BS**. Advances in the Treatment of Neuropathic Pain. In: Carter GT: *Physical Medicine and Rehabilitation Clinics of North America*. May WB Saunders Inc, 2001.
17. **Galer BS** and Harden, RN. Motor abnormalities in CRPS: A neglected but key component. In: Harden RN, Baron R, and Janig W: *Complex Regional Pain Syndrome. Progress in Pain Research and Management*. Vol 22. IASP Press, Seattle, 2001.
18. **Galer BS**, Gammaitoni A, Alvaraz, N. Pain. Scientific American Medicine, WebMD. 2001, Chapter 10, Section XIV.
19. **Galer BS**, Gammaitoni A. Targeted Peripheral Analgesics. In: Wallace MS and Staats PS: *Pain Medicine & Management- Just the Facts*. McGraw-Hill, 2004.

Invited Review Articles / Book Chapters (cont'd)

20. **Galer BS**, Gammaitoni A, Alvaraz, N. Topical Analgesics. In: Aronoff GM. *Handbook On Pharmacological Management of Chronic Pain*. Wavecrest Publ, 2005.
21. Alvaraz, N, Gammaitoni A, **Galer BS**. In: Postherpetic Neuralgia in the Cancer Patient. *Cancer Pain*. In press.

## **Bradley Stuart Galer, M.D.**

### **Invited Commentaries/ Editorials**

1. **Galer BS.** Opioids and Chronic Nonmalignant Pain. *APS Journal* 2:207;1993.
2. **Galer BS.** Diabetic Neuropathy. *American Pain Society Bulletin* 3:18;1993.
3. **Galer BS.** Commentary on Sumatriptan and Headache. *APC Journal Club* 1993.
4. **Galer BS.** Commentary on Carpal Tunnel Syndrome. *Pain Med J Club* 1(2):72-73,1995.
5. **Galer BS.** Commentary on Headache and Psychological Profile. *Pain Med J Club* 2(2):71-72;1996.
6. **Galer BS.** Commentary on Tricyclic Antidepressants for Pain. *Pain Med J Club* 2(6):298-299;1996.
7. **Galer BS.** Commentary on The Topical Lidocaine Patch. *Drugs*, in press.

### **Letters-to-the-Editor**

1. **Galer BS.** Reflex Sympathetic Dystrophy Syndrome [letter]. *Lancet*, 344:691; 1994.
2. **Galer BS.** Chronic Pain is Real [letter]. *Neurology*,48:1739;1997.
3. **Galer BS.** Reflex Sympathetic Dystrophy Syndrome [letter]. *Pain*, 67:209;1997.
4. **Galer BS.** Complex Regional Pain Syndrome [letter]. *Pain*, 84:113;2000.
5. Dworkin RH, **Galer BS**, Rowbotham MC. Herpes Zoster. *New Engl J Med*. 2000;343:221-222.
6. **Galer BS.** Response to: Response to letter regarding 'impaired self-perception of the hand in complex regional pain syndrome.' *Pain*, 117: 242.

### **Invited Book Reviews**

1. **Galer, BS.** American Pain Society J. Review of Olesen, J and Schoenen, J (eds): *Frontiers in Headache Research, Vol 3, Tension-Type Headache*. Raven Press, 1994.
2. **Galer, BS.** American Pain Society J. Review of Olesen, J, Tfelt-Hansen, P, and Welch, KMA (eds): *The Headaches*. Raven Press, 1994. Summer 1994, p 144.
3. **Galer, BS.** American Pain Society J. Review of Olesen, J (ed): *Frontiers in*



*Headache Research, Vol 4, Headache Classification and Epidemiology*. Raven Press, 5(2);1995, p 19.

4. **Galer, BS.** American Pain Society Bulletin. Review of Janig, W. and Stanton-Hicks, M. (eds): *Reflex Sympathetic Dystrophy: A Reappraisal- Progress in Pain Research and Management*. IASP Press, 1996. 6(3);1996, p 16.
5. **Galer, BS.** Annals of Neurology. Review of Portenoy, RK and Kanner, RM (eds): *Pain Management: Theory and Practice- Contemporary Neurology Series (Vol 48)*. F. A. Davis, 1996. 40(4);1996:123.

Abstracts (abbreviated- stopped listing after 2002)

1. Portenoy RK, **Galer BS**, Salomon O, Freilich M, Berger M, Finkel JE, Lipton RB, Milstein D. Identification of Epidural Neoplasm: Radiography and Bone Scintigraphy in the Symptomatic and Asymptomatic Spine. *Neurology* 38 (Suppl 1):210;1988. Presented at the 40th Annual Meeting of the Academy of Neurology, 1988.
2. Lipton RB, **Galer BS**, Dutcher JP, Meller F, Pahmer V, Arezzo JC, Wiernik PH, Schaumburg HH. Large and Small Fiber Type Sensory Dysfunction in Patients with Cancer. *Neurology* 39(Suppl1):320;1989. Presented at the 41st Annual Meeting of the Academy of Neurology, 1989.
3. Breitbart W, Portenoy RK, **Galer BS**, Passik S. Pain in the Ambulatory AIDS Patient: Prevalence and Psychosocial Correlates. Presented at the 38th Annual Meeting of Psychosomatic Medicine, 1991.
4. **Galer BS**, Miller KV, Rowbotham MC. Response to Intravenous Lidocaine Infusion Differs Based on CNS or PNS origin of Neuropathic Pain. *Neurology* 42 (Suppl 3):391;1992. Presented at the 44th Annual Meeting of the Academy of Neurology, 1992.
5. Rowbotham MC, **Galer BS**, Allen RR, Davies PJ, Verkempinck CM, Keller LR. Lidocaine Patch for Postherpetic Neuralgia: Results of a Double-blind Placebo Controlled Trial. Presented at the 7th World Congress of Pain, Paris, France, 1993.

Abstracts (abbreviated- stopped listing after 2002)

6. Stang PE, Von Korff M, **Galer BS**. Chronic Headache Medication Use. Presented at the American Society for Clinical Pharmacology and Therapeutics, 1993.
7. **Galer BS**. Topical Lidocaine Relieves Peripheral Neuropathic Pain. Presented at the American Academy of Neurology, May 1995.
8. **Galer BS**, Kitahara M. Intramuscular Stimulation for the Treatment of Chronic Headache. American Association for the Study of Headache, June 1995.

## **Bradley Stuart Galer, M.D.**

9. Rowbotham MC, Davies P, Venkerpink, C, **Galer BS**. Randomized, double-blind, placebo controlled multicenter study assessing the efficacy of topical lidocaine patches in patients with postherpetic neuralgia. International Association for the Study of Pain, August 1996.
10. Kitahara M, Butler S, Rapp S, **Galer BS**. Controlled study of Intramuscular stimulation for chronic tension type headache. International Association for the Study of Pain, August 1996.
11. Butler S, **Galer BS**. Signs and symptoms of reflex sympathetic dystrophy (complex regional pain syndrome, type 1) following surgery and immobilization. International Association for the Study of Pain, August 1996.
12. Devers A, **Galer BS**. Open-label Trials of Topical Clonidine Gel for the Treatment of Postherpetic Neuralgia and Complex Regional Pain Syndrome. Presented at the American Pain Society, November 1998.
13. Harden N, Bruehl S, **Galer BS**, Salz S, Bertram M, Backonja M, Gayles, R, Stanton-Hicks M, Rudin. External Validation of IASP Diagnostic Criteria for Complex Regional Pain Syndrome and Proposed Research Diagnostic Criteria. Presented at the American Pain Society, November 1998.
14. **Galer BS**, Keran C, Frisinger, M. Pain Medicine Education Among American Neurologists: A Need for Improvement. American Academy of Neurology, April 1999, Toronto Canada.
15. Devers A, **Galer BS**, Topical Lidocaine Patch Relieves a Variety of Neuropathic Pain Conditions: An Open Label Pilot Study. World Congress of Pain, August 1999, Vienna Austria.
16. **Galer BS**, Twilling LL, Harle J, Cluff, R, Rowbotham MC. Efficacy of Riluzole in the Treatment of Neuropathic Pain Conditions. American Pain Society, October 1999, Fort Lauderdale Florida.

### **Abstracts (abbreviated- stopped listing after 2002)**

17. **Galer BS**, Jensen M, Ma T, Davies PS, Rowbotham MC. The Lidocaine 5% Patch Effectively Treats All Neuropathic Pain Qualities: Results of a Randomized Vehicle-Controlled, Double-blind Study Using the Neuropathic Pain Scale, April 2002, American Pain Society.
18. Lidocaine Patch 5% Treats All Neuropathic Pain Qualities: Results of a Randomized Clinical Trial Using the Neuropathic Pain Scale. American Academy of Pain Medicine. February 2002.

19. Lidocaine Patch 5% Treats All Neuropathic Pain Qualities: Results of a Randomized Clinical Trial Using the Neuropathic Pain Scale. American Academy of Neurology. April 2002.
20. Lidocaine Patch 5% Treats All Neuropathic Pain Qualities: Results of a Randomized Clinical Trial Using the Neuropathic Pain Scale. American Society of Regional Anesthesia. April 2002.
21. OPEN-LABEL STUDY OF THE EFFECTIVENESS AND SAFETY OF LIDOCAINE PATCH 5% (LIDODERM) IN PATIENTS WITH PAINFUL DIABETIC NEUROPATHY. World Congress on Pain. August 2002.
22. EFFECTIVENESS OF LIDOCAINE PATCH 5% ON VARIOUS PAIN QUALITIES ASSOCIATED WITH DIABETIC NEUROPATHY: A PROSPECTIVE TRIAL USING THE NEUROPATHIC PAIN SCALE. World Congress on Pain. August 2002.
23. Assessment of Opioid-Sparing and Tolerance in Chronic Non-Malignant Pain Patients with the NMDA-Enhanced Analgesic EN3231: Results of a 3-month randomized, controlled trial World Congress on Pain. August 2002.
24. Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Single-Dose Study of Oxycodone 10 mg/Acetaminophen 325 mg vs Oxycodone 20 mg Alone in Patients With Acute Pain Following Third Molar Extraction. American Association of Oral and Maxillofacial Surgeons (AAOMS). October 2002.
25. FIXED TID DOSING OF NEW FORMULATIONS OF OXYCODONE/ACETAMINOPHEN SIGNIFICANTLY REDUCES PAIN INTENSITY AND PAIN INTERFERENCE WITH QUALITY OF LIFE IN PATIENTS WITH CHRONIC LOW BACK PAIN. American Osteopathic Association. October 2002.
26. Efficacy and safety of EN3231, an NMDA-enhanced analgesic: results of a 3-month randomized controlled trial demonstrate faster resolution of opioid related side effects compared to morphine alone. American Society of Regional Anesthesia and Pain Medicine (ASRA). November 2002.

Abstracts (abbreviated- stopped listing after 2002)

27. EN3231, AN NMDA-ENHANCED ANALGESIC, PROVIDES COMPARABLE ANALGESIA WITH A 50% REDUCTION IN OPIOID DOSE VS MORPHINE ALONE IN ARTHRITIS PATIENTS. American Society of Regional Anesthesiology. November 2002.
28. Effectiveness and Safety of the Lidocaine Patch 5% as Add-On Treatment to Gabapentin in Patients With Postherpetic Neuralgia, Diabetic Neuropathy, or Low Back Pain: Results of a Prospective, Open-Label, Multicenter Study. American Society of Consultant Pharmacists. November 2002.

## **Bradley Stuart Galer, M.D.**

29. Lidocaine Patch 5% Reduces Pain Interference with Quality of Life in Patients With Painful Diabetic Neuropathy: A Prospective, Multicenter, Open-Label Pilot Trial. American Society of Consultant Pharmacists. November 2002.
30. EFFECTIVENESS AND SAFETY OF THE LIDOCAINE PATCH 5% AS ADD-ON TREATMENT OR MONOTHERAPY IN PATIENTS WITH PAIN FROM OSTEOARTHRITIS OF THE KNEE. American Society of Consultant Pharmacists. November 2002.
31. 18- AND 24-HOUR DAILY DOSING OF THE LIDOCAINE PATCH 5% MAINTAINS SAFETY MARGIN, TOLERABILITY, AND LACK OF SENSORY CHANGES IN HEALTHY ADULTS. American Academy of Physical Medicine & Rehabilitation. November 2002.
32. EFFECTIVENESS AND SAFETY OF THE LIDOCAINE PATCH 5% IN PATIENTS WITH PAINFUL DIABETIC NEUROPATHY: A PROSPECTIVE, OPEN-LABEL PILOT STUDY. 5<sup>th</sup> International Neuropathic Pain Meeting. November 2002
33. EFFECTIVENESS AND SAFETY OF THE LIDOCAINE PATCH 5% AS ADD-ON OR MONOTHERAPY IN PATIENTS WITH PAIN FROM OSTEOARTHRITIS: A PROSPECTIVE, MULTICENTER, OPEN-LABEL STUDY. 5<sup>th</sup> International Neuropathic Pain Meeting. November 2002
34. LIDOCAINE PATCH 5% EFFECTIVELY TREATS COMMON PAIN QUALITIES REPORTED BY PATIENTS WITH ACUTE, SUBACUTE, AND CHRONIC LOW BACK PAIN. 5<sup>th</sup> International Neuropathic Pain Meeting. November 2002
35. IMPACT OF LIDOCAINE PATCH 5% ON PAIN INTENSITY AND PAIN RELIEF WHEN USED IN COMBINATION WITH GABAPENTIN IN 3 CHRONIC PAIN STATES. 5<sup>th</sup> International Neuropathic Pain Meeting. November 2002
36. EVALUATION OF THE IMPACT OF THE LIDOCAINE PATCH 5% ON QUALITY OF LIFE IN PATIENTS WITH PAIN FROM OSTEOARTHRITIS. American Society of Hospital Pharmacist . December 2002.

### **Abstracts (abbreviated- stopped listing after 2002)**

37. LIDOCAINE PATCH 5% IMPROVES PAIN INTENSITY AND PAIN RELIEF WHEN USED IN COMBINATION WITH GABAPENTIN IN 3 CHRONIC NEUROPATHIC PAIN STATES. American Society of Hospital Pharmacist . December 2002.
38. A PROSPECTIVE, MULTICENTER, OPEN LABEL TRIAL OF THE LIDOCAINE PATCH 5% IN PAINFUL DIABETIC NEUROPATHY. American Society of Hospital Pharmacist . December 2002.
39. EN3231, an NMDA-ENHANCED ANALGESIC, IS SAFE AND EFFECTIVE FOR CHRONIC PAIN MANAGEMENT IN THE ELDERLY. American Society of Hospital Pharmacist. December 2002.

[stopped reporting Abstracts/Posters 2002]